EVANS VACCINES

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K. Midthun, M.D., Director
Office of Vaccines Research & Review, HFM-99
Center for Biologics Evaluation & Research
Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852-1448,
U.S.A.

June 27, 2003

Re: Team Biologics Inspection of Evans Vaccines Limited, Gaskill Road, Speke, Liverpool, L24 9GR, U.K., June 2-10, 2003
Response to Form FDA 483

Dear Dr. Midthun

Evans Vaccines is providing responses to observations issued in Form FDA483 on June 10, 2003 by Team Biologics Investigators, Mrs. Omotunde Osunsanmi and Dr. Robert W. Jennings, and CBER Investigators, Dr. Robin Levis and Mr. Jonathan McInnis, during the inspection at Evans Vaccines Limited, Gaskill Road, Speke, Liverpool, L24 9GR, U.K. (BL 1615).

The responses to the observations in Form FDA 483 are presented in the following manner:

Observation: Observation number and Observation, as set in Form FDA 483.
Response: A response to the observation. Within each response Evans Vaccines provides corrective and preventative actions and a commitment date.

Evans Vaccines will provide quarterly status reports on activities to meet our quality commitments.

Evans Vaccines would like to meet with the agency as soon as possible to review Evans Vaccines' global and systemic approach. At this meeting we would welcome the opportunity to present to the agency our Quality Systems Improvements Program.

Evans Vaccines is committed to continuous quality system improvements. In May 2003 Evans Vaccines launched an enhanced program in support of our existing quality system improvement plan. Quality systems improvements will be addressed on a global basis to assure consistency in the applications of cGMPs across the manufacturing sites program will be an ongoing global initiative for the company.

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Parsippany NJ USA

Quality System Improvement Program (QSIP)

As part of Evans Vaccines' commitment to continuous quality improvement, we recognize our responsibility with respect to understanding any gaps and required improvements in our quality systems. We achieve this level of understanding of our quality systems through a proactive review of our systems and processes, and effective involvement and participation on quality improvements at all levels throughout the organization.

We have recognized some areas within our existing operations, which require improvement. The high priority quality system elements have been incorporated into the Liverpool site quality objectives for the financial year April 2003-March 2004, following endorsement by the Evans Vaccines (Powderject) board of directors. These quality system objectives are also applicable across the Powderject group.

The Quality System Improvement Program (QSIP) objective for 2003/2004 is to redevelop and introduce robust quality systems for:

- Failure investigations, Corrective and Preventative actions
- Engineering Quality
- Documentation Management and Control
- Validation and Requalification
- Vendor Assurance
- IT Compliance

Each of the systems has been assigned to a site operations manager who reports directly to one of the Liverpool site executive management team members. In addition to one-on-one discussions between the operations manager and their site executive line manager, the site executives also have a defined program to monitor delivery against the objective, whereby the operations manager responsible for the delivery of the objective is required to present updates to the Liverpool site executive management committee in accordance with a defined plan.

We recognize that quality improvement is a continuous process. We continue to review our systems and processes and implement improvements throughout all our operations. The quality system objectives for this year do however recognize that we need to prioritize, so that we have a manageable program of quality system improvements, which will deliver sustainable improvements throughout our business.

In order to further enhance our understanding of the gaps, and improvements required to sustain our quality systems, and furthermore, to benefit from additional expertise in developing our way forward, we have selected the [redacted] to assist us.

[redacted] have specific expertise to enable them to support our quality improvement initiative. Attachment 6.1 (Page 530) contains the Quality System Improvement Plan (QSIP).

The QSIP reflects the desire of Evans Vaccines to improve management control over the quality system, as part of its overall business responsibility and as required by FDA. As such, this initiative was commissioned by Evans Vaccines (Powderject) management committee and features their oversight of the process, review of the findings and support for improving quality systems as may be revealed by this study.

If you should have any questions, please contact Dr. Jim C. Williams, Vice President U.S. Regulatory Affairs and Authorized Official, Liverpool facility at 978-836-7006 / 608-231-3150 or Mr. John O'Brien (Head of Operations, Liverpool facility) at +44 151 705 5083.

Yours sincerely

Mr. A. H. Sneddon
Site Director

Enc. Mrs. Omotunde Osunsanmi, CSO, CDER
Dr. Robert W. Jennings, CSO, CDER
Dr. Robin Levis, Regulatory Coordinator, CBER
Mr. Jonathan McInnis, Biologist, CBER
Dr. J. C. Williams, Vice President U.S. Regulatory Affairs / Authorized Official
Mr. J. O'Brien, Head of Operations, Evans Vaccines Limited.